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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/064,710 | 08/08/2002 | Richard Joseph Sunberg | 9008 | 1875 |
| 27752 | 7590 | 06/01/2004 | EXAMINER | |
| THE PROCTER & GAMBLE COMPANY INTELLECTUAL PROPERTY DIVISION WINTON HILL TECHNICAL CENTER - BOX 161 6110 CENTER HILL AVENUE CINCINNATI, OH 45224 | | | CHOI, FRANK I | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1616 | | |
| DATE MAILED: 06/01/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/064,710 | SUNBERG ET AL. |
| | Examiner | Art Unit |
| | Frank I Choi | 1616 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 March 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-13 and 15-18 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-13 and 15-18 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____.

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The Specification does not appear to disclose that the activated carbon is a thermoset phenolic resin.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 15-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for diminishing the risk of pregnancy and diminishing the risk of certain disclosed STDs with respect to disclosed known agents which are used to reduce the risk of pregnancy and STDs and condoms and diaphragms and in the appropriated administrative site, does not reasonably provide enablement for the use of activated carbon (AC) for the prevention of pregnancy or STDs, including reducing the risk thereof or all forms of administration or barrier agents in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The nature of the invention:

The invention is directed to compositions, kits and methods of preventing pregnancy or STDs by administering activated carbon.

The state of the prior art and the predictability or lack thereof in the art:

The prior art of record does not appear to show the effectiveness of activated carbon for prevention of pregnancy or STDs. Also, Banba, cited below, discloses a composition containing activated carbon which requires antibiotics to inhibit bacterial growth and which maintains the viability of sperm. As such, predictability in the art appears to be low.

The amount of direction or guidance present and the presence or absence of working examples:

Other than a general statement that AC is known to bind to pathogens, the only pathogens which are disclosed to bind to AC is *Neisseria gonorrhoeae* and *Chlamydia trachomitis*. With respect to pregnancy, the Specification indicates that sperm has a strong affinity for AC. The Examples set forth in the Specification appear to be only prophetic in nature as opposed to actual data as no actual results appear to be given. As such, the only information provided is that pathogens and sperm bind to AC, however, no data is provided as to whether this has any effect on pregnancy or STDs.

The breadth of the claims and the quantity of experimentation needed:

The claims broadly claim prevention of pregnancy and sexually transmitted disease by administration to a subject in need thereof. As such, in light of the above, one of ordinary skill in the art would be required to do undue experimentation in order to determine which pathogens bind to AC and whether is effective in preventing STDs and to determine whether binding of sperm to AC is effective in preventing pregnancy, and determining which is the appropriate method of administration, or what other agents would serve as barriers.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that predictability in the art is not low, however, Applicant presents no references which dispute this finding. The fact that activated carbon is a known composition for use in filtration and odor absorbing does not support a finding that it use as claimed is highly predictable. Applicant's argue that it is known in the art that activated carbon binds to many different kinds of bacteria, yeast, toxins, dyes, antibiotics and other chemical substances, however, Applicant does not provide evidence of the same. Further, Applicant makes no showing that activated carbon binds to viruses. Applicant argues that the examples show effectiveness of the activated carbon and are actual experiments, however, none of the examples show actual results. If the examples are actual experiments, than it should be no problem for Applicant to provide the data and results of those experiments. Further, Examiner is not basing the rejection solely on the fact that the examples are prophetic in nature. Examiner has provided sufficient reasoning as indicated above to require that one of ordinary skill in the art could not use the genus as a whole without undue experimentation. Applicant argues that it has disclosed various embodiments , however, the embodiments again do not show actual results and appear to be largely limited to bacteria and sperm. Also, none of the claims indicate that the composition once applied is removed. See *In re Armbruster*, 185 USPQ 152, 153 (CCPA 1975) ("[A] specification which describes' does not necessarily also enable' one skilled in the art to make or use the claimed invention.").

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13,15-18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the

elements. See MPEP § 2172.01. The omitted elements are: the claims indicated a safe and effective amount of activated carbon but do not indicate what is the effect of the activated carbon. Examiner has duly considered Applicant's arguments but deems them unpersuasive. If by citation to various parts of the Specification, Applicant means that the amount is safe and effective to bind the pathogen or sperm and reduce the risk of STD's or pregnancy, respectively, then Applicant should state the same in the claim.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4,7,10,17,18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Banba (US Pat. 4,356,259).

Banba expressly discloses a container containing activated carbon, sodium bicarbonate, glucose, streptomycin and sulpenicillin falling within the scope of applicant's claims (Example 1).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products that contain the same exact

ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Examiner has duly considered Applicant's arguments but deem them unpersuasive.

Examiner reminds Applicant that in a 102/103 inherency rejection, the *Graham v. John Deere* factor's are inapplicable. As such, Applicant's arguments regarding the use of the prior art composition versus the use of the claimed composition do not overcome the rejection herein. Further, the differences in intended use or reasons for use of the composition or components by the prior art and the claimed invention does not take away from the fact that the composition itself is expressly disclosed by the prior art. Applicant has made no showing that the limitations "spermicidal agent", "anti-sexually transmitted disease agent" or "surfactant agent, anti-metabolite agent, competitive binding inhibitor agent and mixtures thereof" do not include the components set forth in the prior art.

Claims 4,5,7,10,11-13,17,18 rejected under 35 U.S.C. 103(a) as being unpatentable over Banba (US Pat. 4,356,259) in view of DeLiso et al. (US Pat. 5,597,617).

Banba expressly discloses a container containing activated carbon, sodium bicarbonate, glucose, streptomycin and sulpenicillin falling within the scope of applicant's claims (Example 1). Further, Banba discloses that the activated carbon is used to absorb harmful substances such as organic wastes (Column 2, lines 29-33).

DeLiso et al. discloses an activated carbon on a substrate which is strong, temperature resistant, resistant to chipping or flaking and highly adsorptive where the activated carbon is formed from phenolic thermoset resin and the substrate includes alumino-silicates, silicates, titanates, zironates, zirconia-spinel, magnesium alumino-silicates, alumina, spinel, mullite and

cordierite (Column 2, lines 42-48, Column 3, lines 23-32, Column 4, lines 40-58, Examples 1-6, 11-13, 15, 16, Claims 1, 2,11).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of activated carbon which is coated on a substrate or particle. However, the prior art amply suggests the same as it is disclosed in the prior art to use activated carbon for absorbing harmful substances such as organic wastes and to coat activated carbon on inorganic oxides, such as silicates. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the activated carbon coated on inorganic substrates would exhibit greater absorption of harmful substances.

To the extent that Applicant's argument apply to this rejection, Examiner has duly considered the same but deem them unpersuasive.

The rejected claims herein are directed to composition claims, as such, the intended use or reasons for using the specific components need not be the same as that of the claimed composition. The prior art as indicated above discloses and suggests the claimed composition itself regardless of Applicant's reasons for employing the claimed composition or components thereof. Applicant has made no showing that the limitations "spermicidal agent", "anti-sexually transmitted disease agent" or "surfactant agent, anti-metabolite agent, competitive binding inhibitor agent and mixtures thereof" do not include the components set forth in the prior art.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 4,6-8,10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dodd et al. (US Pat. 6,344,218).

Dodd et al. expressly disclose a skin sanitizing and deodorizing composition containing activated carbon as the deodorizing agent, nonoxynol-9 as the sanitizing agent, and gums, celluloses, bentonite and/or aluminum silicates as thickeners, and water falling within the scope of applicant's claims (Claims 1,2,21).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Claims 4-8, 10-13, 17,18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dodd et al. (US Pat. 6,344,218) in view of DeLiso et al. (US Pat. 5,597,617).

Dodd et al. expressly disclose a skin sanitizing and deodorizing composition containing activated carbon as the deodorizing agent, nonoxynol-9 as the sanitizing agent, and gums, celluloses, bentonite and/or aluminum silicates as thickeners, and water falling within the scope of applicant's claims (Claims 1,2,21). Further, Dodd et al. discloses that composition is packaged in a container (Column 25, lines 36-54).

DeLiso et al. discloses an activated carbon on a substrate which is strong, temperature resistant, resistant to chipping or flaking and highly adsorptive where the activated carbon is formed from phenolic thermoset resin and the substrate includes alumino-silicates, silicates, titanates, zironates, zirconia-spinel, magnesium alumino-silicates, alumina, spinel, mullite and

cordierite (Column 2, lines 42-48, Column 3, lines 23-32, Column 4, lines 40-58, Examples 1-6, 11-13, 15, 16, Claims 1, 2,11).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of activated carbon which is coated on a substrate or particle or a kit. However, the prior art amply suggests the same as it is disclosed in the prior art to use activated carbon for odor controlling, to coat activated carbon on inorganic oxides, such as silicates, and to package the same in containers. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the activated carbon coated on inorganic substrates would exhibit greater absorption of odors and that the composition can be conveniently placed in a container which would make carrying and administrating the composition easier.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached at (571)272-0602. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC
May 27, 2004

FRANK N. CHOI
PRIMARY EXAMINER
A.U. (6/6)

Frank Choi